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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,715	01/12/2000	CLARE PASSMORE	6442/60557	7077

7590

11/19/2001

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EXAMINER

BERMAN, ALYSIA

ART UNIT

PAPER NUMBER

1619

DATE MAILED: 11/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/423,715

Applicant(s)

PASSMORE ET AL.

Examiner

Alysia Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20,23 and 25-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9,11-20,25-27 and 30 is/are rejected.
- 7) ☒ Claim(s) 10,28 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Receipt is acknowledged of the amendment filed September 24, 2001. Claims 21, 22 and 24 have been canceled. Claims 1-20 and 23 have been amended. Claims 25-30 have been added. Claims 1-20, 23 and 25-30 are pending.

Specification

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(1). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. At page 9, lines 1-3, the specification describes copolymers of methyl vinyl ether with maleic anhydride, but does not describe the use of methyl vinyl ether by itself. Therefore, the specification is not enabled for the use of methyl vinyl ether as a gelling or suspension agent when not part of a copolymer with maleic anhydride.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 11-13, 16 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 11, 12 and 16 are indefinite because of the term "derivative". It is unclear what Applicant intends to encompass by derivatives of arylpropionic acid, aryl acetic acid, modified cellulose and methacrylate. Although the specification provides examples of arylpropionic acid derivatives and aryl acetic acid derivatives at page 7, lines 10-13, the claims are not limited to these preferred embodiments. Further, the specification provides no guidance as to what is encompassed by modified cellulose and methacrylate derivatives. The metes and bounds of the claims cannot be determined.

7. Claim 13 is indefinite because it recites a Markush group but is not written in proper Markush form. The proper claim language for a Markush group is, for example, "selected from the group consisting of A, B and C," or "wherein A is B or C." Appropriate correction is requested.

8. Claims 12 and 29 recite the limitation "the third ... pharmacologically active agents". There is insufficient antecedent basis for this limitation in the claim. None of the claims that claim 12 depends from recite a third pharmacologically active agent.

9. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as

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to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 29 recites the broad recitation aryl carboxylic acids, and the claim also recites ibuprofen, ketoprofen, fenoprofen, flurbiprofen and etodolac which are the narrower statements of the range/limitation.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 3, 6, 9, 11, 14-20 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,206,021 (021).

US '021 is directed to oil-in-water emulsions that contain pesticidal substances and can be used for topical application to crops using a spray mixture (title and col. 15, lines 22-27). At column 8, line 65 to column 9, line 13, US '021 discloses that the compositions may be in the form of a eutectic mixture of lipophilic pesticidal substances. The melting point of the eutectic mixture is generally between about -20° and 30° C,

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which is encompassed by the instantly claimed range of less than 40° C melting point of the eutectic mixture.

For antifungal agents, antibacterial agents, etc., see column 9, lines 44-64. For arylpropionic acid derivatives and aryl acetic acid derivatives, see column 10, lines 1-9. The reference teaches at column 10, lines 27-29 that an organic solvent may be used but is not necessary. Therefore, the reference teaches the limitation of claim 9 excluding a co-solvent or additional oil phase other than the eutectic mixture. However, if an organic solvent is used, the composition of US '021 would then contain an additional pharmaceutically acceptable component as in instant claims 3 and 6.

For gelling or suspension agents, see the thickeners methylcellulose and colloidal silica disclosed at column 14, lines 7-20. US '021 teaches that biopolymers obtained by the fermentation action of *Xanthomonas* bacteria are useful in the compositions as thickeners. It is known in the art that the biopolymer xanthan gum produced by *Xanthomonas* bacteria is commonly used as a thickener. Therefore, US '021 implies the use of xanthan gum in the compositions. For non-ionic surfactants, see column 12, line 47 to column 13, line 49. For other surfactants, see column 13, lines 50-58.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-9, 11-20, 25-27 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,206,021 (021).

US '021 teaches all the limitations of the claims as stated in the 35 U.S.C. 102(b) rejection above. It does not teach the melting point of each of the pharmacologically active and/or pharmaceutically acceptable components or the pharmaceutically acceptable components of claim 13. It is within the skill in the art to select optimal parameters of a composition in order to achieve a beneficial effect. Fatty acids, fatty alcohols, menthol, thymol and their esters are commonly used components of topical compositions. Therefore, absent evidence of unexpected results, the melting points of the pharmacologically active and/or pharmaceutically acceptable components and the pharmaceutically acceptable components of claim 13 do not render the claims patentable over the prior art.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '021 using pharmacologically active and/or

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pharmaceutically acceptable components with any suitable melting points with the reasonable expectation of obtaining a stable eutectic emulsion.

Allowable Subject Matter

15. Claims 10, 28 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Claim 23 is allowed.

Conclusion

16. Applicant is advised that should claims 3-5 and/or 26 be found allowable, claims 6-8 and/or 27 will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 6 is a substantial duplicate of claim 3. Claim 7 is a substantial duplicate of claim 4. Claim 8 is a substantial duplicate of claim 5. Claim 27 is a substantial duplicate of claim 26.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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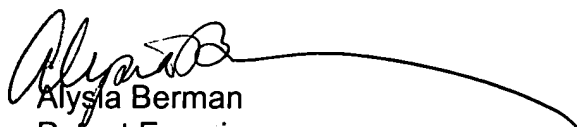
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

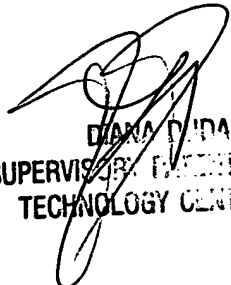
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached during core hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3704 or 703-305-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.


Alysia Berman
Patent Examiner
November 15, 2001


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